



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0038; FRL-9328-7]

Environmental Protection Agency, Department of Health and Human Services and Department of Agriculture; Memorandum of Understanding Regarding Genetically Engineered Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces that pesticide-related information submitted to EPA's Office of Pesticide Programs (OPP) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including information that may have been claimed as Confidential Business Information (CBI) by submitters in accordance with 40 CFR 2.309(c) and 2.308(h)(2) will be shared with the Department of Human Services (HHS) and the U.S. Department of Agriculture (USDA). HHS's Centers for Disease Control and Prevention and the Food and Drug Administration (FDA) will perform work for OPP under a Memorandum of Understanding (MOU). The MOU will support and encourage cooperation and communication between USDA, FDA, and EPA in the regulatory oversight over genetically engineered plants and the foods derived from such plants. Under the MOU, USDA's office of Animal and Plant Health Inspection Service/Biotechnology Regulatory Services (APHIS/BRS) and EPA agree to share with each other information about genetically engineered plants and the foods derived from such plants, including non-public information exempt from public disclosure usually referred to as "confidential business information" and/or "trade secrets."

FOR FURTHER INFORMATION CONTACT: Mario Steadman, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-8338; e-mail address: *steadman,mario@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action applies to the public in general. As such, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0038. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805. A copy of the MOU has been placed in the docket.

II. Brief Summary of the Memorandum of Understanding (MOU)

EPA regulates pesticides in particular plant-incorporated protectants (PIPs). PIPs are pesticidal substances (such as *Bacillus thuringiensis* protein) produced in plants and

the genetic material necessary for their production in plants (such as *cry* genes). EPA grants experimental use permits for field testing and registrations that permit the sale and use of pesticides, including PIPs, in commerce under FIFRA, 7 U.S.C. 136 *et seq.* EPA also issues tolerances or tolerance exemptions that permit pesticide chemical residues in food under section 408 of FFDCA.

The MOU will support and encourage cooperation and communication between USDA, FDA, and EPA in the regulatory oversight over genetically engineered plants and the foods derived from such plants. Under the MOU, USDA/APHIS/ BRS, FDA, and EPA agree to share with each other information about genetically engineered plants and the foods derived from such plants, including non-public information exempt from public disclosure usually referred to as "confidential business information" and/or "trade secrets" (also referred to as "non-public information" in the MOU).

Subject to Units A, B, and C defined in the MOU, an agency shall not further disclose non-public information received under the MOU except with the written permission of the agency from which the non-public information originated.

Under the MOU, USDA/APHIS/BRS would share non-public information including CBI that it receives from private entities pursuant to its biotechnology regulations under 7 CFR part 340 only as described below.

Confidential information provided by USDA/APHIS/BRS may only be shared with FDA and EPA personnel who have been granted access to non-public information by the Director of USDA/APHIS/BRS' Regulatory Operations Division or his/her designate via the APHIS Access Authorization Agreement for Trade Secrets and Confidential Business Information form.

List of Subjects

Environmental protection, Business and industry, Genetically engineered plants, Government contracts, Government property, Memorandum of Understanding, Security measures.

Dated: January 19, 2012.

Michael Hardy,

*Acting Director, Information Technology and Resources Management Division,
Office of Pesticide Programs.*

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